

FEB 28 2002

GENERAL INFORMATION

A. Trade Name

Sandhill Scientific PediaTec™ pH Probe

B. Common/Usual Name

Stomach pH Probe

C. Device Sponsor

Sandhill Scientific, Inc.
9150 Commerce Center Circle, #500
Highlands Ranch, CO 80129
303-470-7020 / 303-470-2975 fax

D. Establishment Registration

2023374

E. Classification

Class I 78 FFT
876.1400 Stomach pH Electrode, Exempt from 510(k)

F. Classification Panel

78, Gastroenterology and Urology Panel

G. This submission is being made for a modification to an existing approved 510(k) to add an indication for use with pediatric populations. See attached memo to Lewis Ward from Linda (Diederich), Vice President, Sandhill Scientific, Inc.

H. Substantial Equivalence

This pediatric pH probe is substantially equivalent to the Sandhill Disposable Internal Reference pH probe cleared under K931963/A, September 28, 1994.

I. Performance Standard

There is currently no performance standard for pH probes.

J. Official Contact

Lewis W. Ward, Consultant
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301

Telephone: 303-530-3279
Fax: 303-530-4774



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2002

Sandhill Scientific, Inc.
c/o Mr. Lewis W. Ward
L. W. Ward and Associates, Inc.
4655 Kirkwood Court
BOULDER CO 80301

Re: K013951
Trade/Device Name: Sandhill Scientific PediaTec™
Pediatric pH Probe
Regulation Number: 21 CFR §876.1400
Regulation Name: Stomach pH electrode
Regulatory Class: I
Product Code: 78 FFT
Dated: November 17, 2001
Received: November 30, 2001

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K013951

Initial 510(k): Sandhill Scientific, Inc. K013951

Device Name: **PediaTec™, Pediatric pH Probe**

Indications for Use:

Used to measure intragastric and intraesophageal pH (hydrogen ion concentration)
in pediatric patients

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Nancy C. Brogan
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013951